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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,078	06/30/2003	Jae-Gu Pan	10981-034	7867
20582	7590	03/29/2005	EXAMINER	
JONES DAY 51 Louisiana Aveue, N.W WASHINGTON, DC 20001-2113			LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/608,078	Applicant(s) PAN ET AL.	
	Examiner David A. Lambertson	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 2 and 11, drawn to a vector comprising a desired gene operably linked to a promoter that can be induced by acetic acid, and a method of producing said desired gene using said vector, classified in class 435, subclass 69.1.
- II. Claims 2 and 11, drawn to a vector comprising a desired gene operably linked to a promoter that can be induced by succinic acid, and a method of producing said desired gene using said vector, classified in class 435, subclass 69.1.
- III. Claims 2 and 11, drawn to a vector comprising a desired gene operably linked to a promoter that can be induced by maleic acid, and a method of producing said desired gene using said vector, classified in class 435, subclass 69.1.
- IV. Claims 2 and 11, drawn to a vector comprising a desired gene operably linked to a promoter that can be induced by fumaric acid, and a method of producing said desired gene using said vector, classified in class 435, subclass 69.1.
- V. Claims 2 and 11, drawn to a vector comprising a desired gene operably linked to a promoter that can be induced by citric acid, and a method of producing said desired gene using said vector, classified in class 435, subclass 69.1.

Claims 1, 3-10 and 12-16 link(s) the inventions of Groups I-V. Upon the election of a group, the respective linking claim(s) will be examined with respect to the elected invention.

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The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 3-10 and 12-16. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. This is NOT an election of species, but rather an election of distinct inventions.

The inventions are distinct, each from the other because of the following reasons:

Inventions Groups I-V are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions related to the specific promoters being used in the vectors of said inventions. In each Group, the methods make use of a different promoter that is responsive to a different organic acid; in order to respond to a different organic acid, the promoters must have distinct nucleic acid sequences that distinguish them from each other, and allow them to be activated differentially by a given

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organic acid. For instance, the acetic acid-responsive promoter of Group I will have a distinct nucleic acid sequence from that of the succinic acid-responsive promoter because it is transcriptionally active in response to acetic acid, not succinic acid; the specific promoter sequence is what allows this responsiveness to occur. The same analysis can be applied to the relationship for each promoter element of Groups I-V: each is a distinct nucleotide sequence that is specifically responsive to a particular organic acid. As a result of these promoters having such distinct nucleotide sequences which are functionally different from each other in that they respond differently to given organic acids, each of the Groups has a different function (i.e., responsiveness to a given organic acid). Furthermore, the use of different promoter elements in each of the claimed methods represents different modes of operation because functionally distinct promoter elements are used in each invention. Finally, distinct and burdensome searches would be required to search each of the inventions of Groups I-V because art reading on the use of a promoter responsive to acetic acid would not necessarily anticipate or make obvious the use of a promoter responsive to succinic acid, these promoters being structurally and functionally distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper.

Furthermore, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore restriction for examination purposes as indicated is proper.

Applicant is reminded that the instant Groups are linked by claims 1, 3-10 and 12-16, and are subject to rejoinder based on the allowability of the linking claims.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
David A. Lambertson  
AU 1636